Adverse Event Reporting Systems, CTMS and CDUS Survey Results: Attachments

Adverse Event Reporting How do you intend to interact with the caBIG AE system? Please describe, if other	
Boston VAHCS	Original Survey: Create a new system that would interface with caBIG
Case Comprehensive Cancer Center	Updated Survey: We are in the process of implementing Oncore by PercipEnz. They are aware of the need of AE reporting along with CTUS/CDUS reporting and will be implementing this in the near future, they are working with other members that use the product to develop this aspect. I don't think I'd call Oncore a legacy system, however.
Chao Family Comprehensive Cancer Center, University of California, Irvine	Original Survey: The AE reporting process at UCI Cancer Center has multiple possible routes: 1) The Cancer Center CRO Manager reports AE to UCI IRB via UCI IRB on-line system. UCI IRB will then distribute the AEs to other related parties, such as PIs; 2.) The Cancer Center Regulatory Officer collects AEs from various sources, such as data managers, UCI IRB, FDA etc., and records the AEs in a home-grown Microsoft Access database; 3.) The Cancer Center does not do CTMS/CDUS reporting. However, for each clinical trial, the study team will prepare NCI Quarterly Progress Reports and DSMB reports, both types of reports include AE reporting.
City of Hope National Medical Center	Updated Survey: Many of the functions envisioned for the caBIG AE system are not currently available in-house. We would be implementing the full implementation of caBIG and, hopefully, it will hav a mechanism for exporting data to our legacy system so that the clinical trials data contained therein would be updated without our having to enter it into two systems. The caBIG system would replace the existing in-house CDUS mapping/formatting programs.
Duke University Medical Center	Updated Survey: We do not have a unified CTMS system to incorporate full or interface implementation. This is one of the challenges that we face even though the desire is to adopt an AE reporting application. Currently, the majority of the information is stored on desktop Microsoft databases. There are a few studies that are supported by our information systems group, however it is unclear at this time whether that application is scalable and can be adopted broadly. Thus it is safer to say that AE reporting capability is highly desirable but the context in which we will implement is currently under discussion.
Mayo Clinic	Version 3.0: We are un-certain as to what the capabilities of the caBIG Adverse Event System are going to be, therefore we are unable to determine how we would interact with the system. We are certainly open to the possibility of using the system or interfacing with the system when we understand it's capabilities.
Memorial Sloan-Kettering Cancer Center	Original Survey: We hope we can make our legacy system fully implement the caBIG model.
NCI	Updated Survey: It has not been stated to us how the CCR will be interfacing with caBIG adverse event system. We are not familiar with the work the group has done to date on this effort.
Northwestern University	Original Survey: We plan on building a caBIG compliant interface between our AE system, which is integrated into our clinical trial system, NOTIS, and the caBIG Adverse Event System. The primary advantage for us in coupling the two is to gain an electronic method for sending AEs securely to the appropriate regulatory agencies.
Oregon Health & Science University	Updated Survey: It really depends on how it turns out. We have adverse event capture and reporting through our legacy clinical trials management system but it is only used by a small group – the rest are handled manually via paper. We have another system that does protocol management and IRB processing, which also handles adverse events communication to the IRB – which we just implemented.
Siteman Cancer Center/ Washington University	Updated Survey: The interaction will depend on the nature of the product developed through the caBIG. The AE system we have in place has been developed recently within the Siteman Cancer Center (SCC) and is in the process of implementation. We are currently developing an interface with our institutional IRB, which has recently gone to an electronic reporting system. If the caBIG offe additional functionality beyond that which we have developed and is able to interact with the IRB system, then we would be interested in utilizing all or part of the caBIG system. Our AE system is a part of our overall clinical trials system, which is a part of our overall administrative database.

University of Colorado CCC	Updated Survey: Although we currently have no adverse events reporting system and I would therefore LIKE to adopt whatever is developed for caBIG whole cloth, we will need to make sure that what is developed meets our institution's needs and fits into the technology infrastructure. We are a SQL Server / .Net shop.
University of Iowa-Holden CCC	Version 3.0: We'd like any data entered into Oncore to be linked to the caBIG system.
University of Minnesota Cancer Center	Updated Survey: We're especially interested in routing AE from our Oncore CTMS to Coop Groups and FDA and receiving Outside Safety Reports that might flow into Oncore.
University of Nebraska Medical Center	Updated Survey: We would need more information about the possibility of interfacing. Our current on-line adverse event reporting system allows information to be imported into our IRB database. Bo systems were designed in-house and work well for us. However, we are open to looking at possibilities if interacting with a larger system. I believe most clinical departments still file med watch reports for reporting to sponsors. Internal, internal fatal, and external reports that meet our reporting requirements are entered on-line. The system does not communicate with sponsors or national agencies. I have noted on page 3 the type of information included in our system. It is a Sybase system.
Yale University	Updated Survey: Test caBIG System, perhaps implement/interface based on testing/evaluation results
Clinical Trials Monitoring Service (CTMS) & Clinical Data Update System (CDUS) Reportin	
What type of CTMS & CDUS data capture and reporting capabilities are currently used at your institution? Comments regarding your institution's reporting capabilities:	
Barbara Ann Karmanos Cancer Institute	Abbreviated Survey: While currently entering via the web-based application, we are interested in creating a secure automated data transfer procedure.
Boston VAHCS	Original Survey: We don't have any one method of transferring AE reports. We use fax, paper. Abbreviated 3.0: Does not currently report to CDUS. Is capable via web service etc.
Chao Family CCC, UC Irvine	Abbreviated 3.0: Although we don't currently do CTMS/CDUS reporting, we are considering doing it the future. We work through Westat/CCSA for our reporting, DCP also is working with Westat.
City of Hope National Medical Center	Updated Survey: For the majority of our trials, we collect data (including AE data) in an internally developed database. This information is then mapped to meet CDUS submission requirements and t system runs checks similar to those done by CDUS. Finally, the data is formatted to meet CDUS specifications for FTP submission. Some of the studies in which we participate are assigned to ACES. Those studies are then reported to CTEP from CTMS.
Mayo Clinic	Version 3.0: We are approximately 85% automated for CDUS reporting, however, it takes several FTE's to complete. Our data is not always clean data when it is sent and often makes it very difficult answer questions from CDUS.

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Memorial Sloan-Kettering Cancer Center	Abbreviated Survey: We used to do it all electronically; now Theradex gets lab data via application-to-application transfer and the rest via ACES (see comments listed under "barriers...". Original Survey: Lab data are entered to CTMS via application-to-application transfer. The rest is entered into ACES. This is a recent change from a long-established practice of entering all data via application-to-application transfer, owing to disagreements with Theradex. We are working on the electronic transfer of ACES data to our system to avoid double data entry, but still regard application-to-application transfer to CTMS as the ideal. Abbreviated 3.0: We have trials that require CTMS reporting, and trials that require CDUS reporting. With CTMS trials, we have switched recently from automatic submission of all data to automatic transmission of lab data only. Non-lab data are now entered into ACES, necessitating double data entry. We will soon implement transfer of data from ACES to our system to eliminate this.
NCI	Updated Survey: We are currently submitting data via multiple systems: paper, web-based application and file transfer. We are currently using the C3D system to transfer data to CTMS/CDUS. Original Survey: We have built extract procedures to generate the CTMS and CDUS submission files from the template CRFs that are used to build each new study. The template CRFs are built with CDE that are published in the NCI's caDSR. These procedures are instantiated for each study to allow for study specific modification/configuration.
Northwestern University	Original Survey: We do not have ACES locally and we had asked about trying to provide them with data electronically several years ago (1999?) and at that time it seemed impossible. With regard to CDUS, we have been unable to work out a secure system for the exchange of data to them (FTP did not allow us to handshake, nor is it secure). Other options, even last year, did not appear to be available electronically. Abbreviated Survey: We would prefer to use XML to send AE reports; we are currently completing implementation of an AE module for our clinical trials database that will interface with our IRB electronically.
Oregon Health & Science University	Abbreviated 3.0: Our CTEP trails require quarterly data submissions via the CDUS system. We do submit reports on the CTEP website. We also file SAE reports via the websites as AdEERS (Adverse Event Expedited Reporting System) reports. Double data entry? We keep hard copies of CRFs for our records.
Siteman CC/ Washington University	Updated Survey: We do not have many studies that fall into this group and, since our system has recently been implemented, have as yet not developed an electronic tool for application-to-application data transfer. The system to enable application-to-application data transfer is currently still in the development stages.Abbreviated Survey Added This Comment: Our capabilities are growing, but this is not one of our highest priority areas. Abbreviated 3.0: We submit our SAEs to both our IRB and our Quality Assurance and Safety Monitoring Committee (QASMC) for review. If any current slides did require CDUS reporting, data would be sent to the database to file for submission.
University of Colorado CCC	Updated Survey: So far as I know, we do not do CTMS reporting.
University of Minnesota Cancer Center	Updated Survey: We currently are not using CTMS and CDUS within the Cancer Center (to our knowledge)
University of Wisconsin, Madison	Updated Survey: Our plan is to have application to application data transfer for both these methods via our Oncore system. We are working as a Consortium to complete Abbreviated 3.0: Allegedly this iteration of Oncore will allow us to extract CDUS required reporting data from Oncore transmit to CDUS via the FTP site however we have not done this to date…..

Adverse Event Reporting Systems, CTMS and CDUS Survey Results: Attachments

Describe any issues/barriers you have had with CTMS and/or CDUS Report systems or opportunities for improvement (e.g. procedures or technical issues with the software):	
City of Hope National Medical Center	Updated Survey: We have had some difficulty with the way in which CDUS expects adverse events data reported. The specification indicates that AEs occurring after the patient is off protocol therapy are to be reported in the LATE_EFFECTS record type. Upon submission, we were told that if the patient has died (after protocol therapy was completed), a grade 5 toxicity needs to be reported in the final course of treatment. After much discussion with CTEP, we submitted based on the specification but some special handling needed to be performed. We anticipated changes being made to the code and/or specification for clarity but that has not been forthcoming. We also find it very frustrating that CDUS goes through several iterations of data validation and, if an error occurs during one of the initial checks, these can be corrected and the next submission will only get you to the next level. It would be helpful for the system to perform a broader range of checks to minimize submissions.
Duke University Medical Center	Updated Survey: (same answer as above) We do not have a unified CTMS system to incorporate full or interface implementation. This is one of the challenges that we face even though the desire is to adopt an AE reporting application. Currently, the majority of the information is stored on desktop Microsoft databases. There are a few studies that are supported by our information systems group, however it is unclear at this time whether that application is scalable and can be adopted broadly. Thus it is safer to say that AE reporting capability is highly desirable but the context in which we will implement is currently under discussion.
Georgetown University	Version 3.0: Recently, we adopted C3D and are working with NCICB to use Oracle Clinical for CTMS trials. It will allow the data to be transferred electronically.
Mayo Clinic	Version 3.0: It would be a bit benefit to have an application that we could run the CDUS reports in house and review to fix all errors before sending it to CDUS. The process of running the report, submitting to CDUS, waiting for the list of errors, correcting the errors and re-running the report and submitting multiple times seems to be in-efficient. We could be much more efficient if we could identify and resolve as many errors as possible in-house before sending to CDUS. Currently, our CTMS data transfer is working well.
Memorial Sloan-Kettering Cancer Center	Abbreviated Survey: We have exported data for years to CDUS and Pharma with no problems; we even exported to Theradex for six years with very few problems. But in the last two or three years we have had endless problems with Theradex and have, for the time being, given up automated data export. The problems seem to stem from the below: 1. Theradex's specifications for data export are extremely vague. They don't have business rules (or at least, they don't publish them if they do). CDUS, for instance, has a huge and highly detailed document that covers virtual every exception. Theradex's spec document is very thin and sketchy compared to CDUS even though they take so much more data. There is documentation for keyed data entry to ACES, but virtually none for electronic transfer. For instance, we have to guess what events are included in concomitant meds (they want surgery, RRX etc). Some table specifications have no notes whatsoever (e.g., infectious disease). It says things like "Not all fields are mandatory" but doesn't say which. They don't say how to handle when some treatment goes over a cycle boundary – do we include in both cycles or not? The answer is yes in this case, but we have to call them up to find out – otherwise they just send us an uninformative error report. 2. Theradex's database structure raises some concerns. There are relatively few coded fields and many text fields (even some primary keys). For instance, toxicity is a text field even though MedDRA codes exist for the CTC defined toxicities. Some of these text fields are absurdly short, e.g. 8 characters to describe a drug, which definitely lead to problems when combinations of drugs are used. When they do use codes, they are often behind CTEP. For instance, although we use the new CTEP prior RX codes, and so does CTEP, we have to reverse-engineer them to the old codes just for Theradex. In addition, there are fields we don't consider useful, e.g. "evaluation number" in Lesion table. We have added some just to pacify Theradex up but some we won't. Even though we have explained our reasons and seemingly secured agreement, they will ding us again and again for it. 3.They don't allow full refresh. All other transfer systems (CDS, pharma) use full data refresh. Theradex insists on incremental refresh, which means you have to keep track of what you already sent them. This has problems especially when they go adjusting the lengths of text primary keys.

NCI	Updated Survey: 1. Clarifications are not always sent in a timely fashion and may even be up to 2 years after data was submitted making it difficult to stay current while correcting older data. 2. Data that we have resubmitted, as a result of internal qa, does not appear to be matched with previously submitted data and results in a clarification of already corrected data. 3. Theradex training could be more informative and occur more frequently due to staff turnover issues. 4. When sending files over for adverse events, CTMS system automatically defaults to description not CTC/CTCAE term. This then generate potentially unnecessary clarification for data alrea entered. 5. Can Theradex ARMS be eliminated in lieu of TACS and subgroup codes? It appears that the ARMS were essential prior to CDUS submission. 6. CTMS appears to have older database systems that are not easily compatible with more current systems/programs. 7. Consider eliminating a biweekly data submission for a per cycle submission especially for cycles that are every 3, 4 or even up to 6-8 weeks. This would assist in supplying the entire picture for a cycle/course and adverse event reporting has been tremendously impacted with AdEERS for timely reporting of expedited adverse events. 8. It would be helpful to have CTMS CRAs be a bit more knowledgeable in CTEP's functioning as a sponsor (i.e.: 1572 process, assigning attributions of AE, etc.). Original Survey: 1. There are several cases where the same piece of information is coded in different (nonstandard) ways for submission to CTMS and CDUS including Race, Gender, Ethnicity, Response, Thera Type Code and Off Study Reason. 2. NSC Agent codes are required for CDUS submission, though no definitive source of these codes seems to be available. CTMS generates their own 8 character abbreviations for study drugs which must be used for submission. There are cases where the same drug is abbreviated differently in different studies. 3. Fixed length submission files pose the typical challenges associated with free form text fields that are part of the key . In the Concomitant Meds and Measure file, only 24 characters are available for submission of the med or measure. Without using some standard, this will lead to loss of data as longer free form values will be truncated to fit and potentially lose distinction 4. CTMS comments can only be attributed to a file/form, not to an item on a file/form. So if a comment is desired for 2 different AEs on the same page, they need to be attributed in the comment, rath than by some key field, like CTC Term and Onset Date. 5. There is not capability to submit units along with labs. The CTMS submission files specify a unit of measure to which local labs must be converted. 6. Data clarifications generated from CTMS submissions are often out of date by the time they are received. This seems to be caused by the sequential nature in which bi-weekly submissions are processed. By the time the clarification is received, the data addressing it may have already been submitted, but not yet processed. This is particularly true during times when CTMS contractor Theradex is busy preparing their CDUS submissions. 7. CTMS has introduced their own abbreviations for terms that are covered by existing standards. For example, in the Prior Therapy Supplement for the Therapy Type Code field the following codes are provided: **CS** Chemotherapy single agent; **BM** Bone Marrow; **CM** Chemotherapy multiple agents; **G** Gene Transfer; **C** Chemotherapy (NOS); **NC** Non-Cytotoxic Chemo; **H** Hormonal Therapy; **AR** Anti-Retroviral Therapy; **I** Immunotherapy; **AS** Antisense Therapy; **V** Vaccine Therapy; **OC** Oncolytic Virotherapy; and **PT** Prior Therapy (NOS). Each of these codes need to be translated to MedDRA code for CDUS submission, yet the 2 character abbreviations are required for submission to CTMS. 8. CDUS submission errors require multiple rounds to process. Each CDUS submission is processed and rejected after receiving some number (or level) of errors. After addressing the identified errors and resubmitting, additional errors that existing in the previous submission may be identified. This process can cycle until all errors are addressed to allow for complete submission processing. It would much easier if the entire submission was processed for errors and all errors were reported in one pass.

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Northwestern University	Original Survey: Any data we enter is directly into their system as we have been unable to learn of a way to send data electronically without double entry. Abbreviated Survey: In general, our coordinators have found the system to be cumbersome and difficult to use. A common complaint is that the queries sent back are coded which require deciphering to read and answer.
Oregon Health & Science University	Updated Survey: Would be nice if interfaces to our inpatient and/or outpatient clinical systems (A2K) could be built to flag/alert whenever a study patient was admitted to the hospital/clinic – thus giving you an awareness that an AE may have occurred and follow up is needed.
Siteman CC/ Washington University	CTMS/CDUS reporting is tedious and requires a review of previous reports to submit appropriate data. For studies that are somewhat outside the norm in some aspect, it can be difficult to determine exactly how to fill the reports out. One problem I have had in the past (at another institution) was that institutional names are not always consistent – some trials might show up under one institutional name, and others might show up under a slightly different name (e.g., having studies under Siteman Cancer Center and also under Washington University – a hypothetical situation).
Theradex Response	I note that one of the 'Issues/Barriers with CTMS' is "Theradex - Vague data export specifications and vague or no table specifications". I suspect that this was written by a person who had seen only the CTMS ACES manual or the Manual for CRFs, which did not have that information because it is not relevant to data entry. There is also a rather detailed CTMS Data Transmission Specifications Manual (downloadable from the CTMS page at www.theradex.com). Programmers at a number of institutions have found this adequate for the development of electronic transfer systems.
System Functionality Comments:	
Boston VAHCS	Abbreviated 3.0: Blank items are already part of the system.
City of Hope National Medical Center	**Homegrown System BITS:** Updated Survey: Adverse Events are not entered in real time into BITS. This data is collected and submitted to BITS by the CRA at the end of each protocol cycle and/or as specified in the protocol. Serious Adverse Events are reported using AdEERS and reported to the institutional monitoring groups (Data Safety and Monitoring Body, Institution Review Board, etc) through a paper-based system. We are currently in the process of developing a system that captures adverse event data from lab values as these are obtained. **Homegrown System COH CDUS:** Updated Survey: Data for our clinical trials are captured and analyzed via BITS (described above). At the CDUS cutoff, data is exported from that system and merged with CTEP-related protocol information and lab information for collaborative studies. This information is then formatting according to CDUS specifications (1 file per study with multiple record types) for uploading via an FTP site. The mapping of data, CDUS specific validations, and file formatting are done by the in-house (COH) CDUS system.
CCC Wake Forest University School of Medicine	Original Survey: Our system is a very rudimentary event logging system linked to the protocol records and patient records. These records can be used to generate check lists and (shortly) IRB forms and is mainly used to insure that all procedures are followed for each event, as well as monthly review by the Clinical Research Oversight Committee. It does not communicate directly with any external body. Any SAE tool would simply have to insert a single record in the logging table.
Memorial Sloan-Kettering Cancer Center	Original Survey: Not quite sure what “AE Expectedness”, “Protocol Status”, “AE relatedness to the Protocol”, and “Risk-benefit Relationship of the research” are in this context, so I assume we don’t collect them, but we may do under different names. We do automated AE grading on imported data, but lab data only. Patient self-reporting via the web is on a trial basis only for one protocol at this stage. Abbreviated 3.0: All are desirable; I can rank them if you like!
NCI	Original Survey: We are collecting the AE observations in C3D. We would like this data to be routed to an AE reporting tool to collect any missing data and handle transformation to reporting format and actual submission.
Northwestern University	Original Survey: The messaging and routing of AE data to the appropriate agency is the driver for us to adhere to the caBIG standards.

Adverse Event Reporting Systems, CTMS and CDUS Survey Results: Attachments

Oregon Health & Science University	Updated Survey: AE reporting is done through customized web reports on our intranet using Crystal Reports and Crystal Enterprise. The data is pulled from our Clinical Trials Data Management system only and not any other systems. Abbreviated 3.0: I think for our needs-we have a stand alone database to capture AE's but its usefulness is limited in that this database does not 'send' or 'receive' information form other systems so study coordinators are usually faced with some amount of redundant data entry as the pull the additional information they need manually from other hospital systems or the paper chart and enter it into our database. All functionalities would be great to have but if I were to prioritize: Our top 3 would be: 1) ability to import clinical data and -or protocol data from other systems....2) Messaging of SAEs .... 3) Routing of AE's....
Siteman CC/ Washington University	Updated Survey: The current system has recently been developed and additional functionality is being developed. (Note: There is one system which replaced a previous homegrown system, that includes AE reporting) Abbreviated 3.0: WU is in the process of implementing internet-based submission for IRB paperwork. Interfaces are in the process of being developed that will ultimately link the SCC and WU IRB internet databases.
University of Nebraska Medical Center	Version 3.0: The in-house AE system is adverse event reporting through our Research Infrastructure Support and Compliance system. It is a web-based product using primarily HTML and runs on Microsoft iis. Contact person is Lee Trant, Associate Director, ITS Application Services (402)559-5664.
Comments regarding your institution's Legacy System:	
Boston VAHCS	Abbreviated 3.0: .NET, XML, Web based portalized system that integrates all of the ORD CTMS business processes from grant submission study closure. Aggregates in one central location all study information from inception to closures. 21 CFR 11 compliant.
Chao Family CCC, UC Irvine	Abbreviated 3.0: There is a significant portion of our studies are prevention studies, which may have a different view about AE categorization/characteristics. Take our colon cancer prevention study as example, we put together an "adhoc" AE event category instead of using CTC v.3. It is very important not to jam prevention into the treatment studies AE paradigm.
Georgetown University	Version 3.0: (Clinical Trial Database Management Applications) We purchased Oracle Clinical and will adopt C3D. Our home grown system will be obsolete. Version 3.0: (Computerized Adverse Event Reporting) This SAE reporting application is developed by our institutional IRB to monitor the SAE submission. It is not only used by oncology department clinical trials, but also other departments.
Mayo Clinic	Version 3.0: We are in the early stages of re-designing and developing a new Clinical Trials system.
Memorial Sloan-Kettering Cancer Center	Abbreviated 3.0: It's open source in as much as we are happy to share the source with anyone. However it is written in Oracle (PL/SLQ, Pro*C and Oracle's 4GL tools) so it's not really open source. Initiatives to rebuild it in Java are beginning but it will be a long time before they bear fruit. The system is not modular, so efforts to componentized it would be required.

<table>
<tr><td>Oregon Health & Science University</td><td>Abbreviated 3.0: Probably not – we use a commercial system that is not tailored for cancer nor does is have mechanisms for incorporating standard vocabularies such as CDEs (at this point). There AE capture in our system and we've populated the AE Category, grade etc from the Common Toxicity Criteria (CTC v.2.0). Fields listed below.

Subject_Adverse_Events

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<tr><td>SYS patient ID</td><td>Not Null</td><td>VARCHAR2(17)</td></tr>
</table>
</td></tr>
<tr><td>Siteman CC/Washington University</td><td>Abbreviated 3.0: Our system for SAE reporting is a secure, password protected system. This system would probably not be one to be contributed to caBIG because several of the key functionalities</td></tr>
<tr><td>University of Minnesota</td><td>Abbreviated 3.0: We and other caBIG participants that use Oncore are committed to making it work seamlessly within the caBIG framework as this evolves.</td></tr>
<tr><td>University of Wisconsin-Madison</td><td>Abbreviated 3.0: We use Oncore which is not a homegrown system so it is not open sourced however they are certainly willing an interested to work with caBIG.</td></tr>
</table>